

IN THE ~~DISTRICT~~ SUPERIOR COURT FOR THE STATE OF ALASKA
AT ANCHORAGE

MARY F. SILVA,
Plaintiff(s),
vs.

HOWMEDICA OSTEONICS CORP. D/B/A
STRYKER ORTHOPAEDICS Defendant(s).

CASE NO. 3AN- 19- 0884 CI

SUMMONS AND
NOTICE TO BOTH PARTIES
OF JUDICIAL ASSIGNMENT

To Defendant: Howmedica Osteonics Corp d/b/a Stryker Orthopaedics

You are hereby summoned and required to file with the court a written answer to the complaint which accompanies this summons. Your answer must be filed with the court at 825 W. 4th Ave., Anchorage, Alaska 99501 within 20 days* after the day you receive this summons. In addition, a copy of your answer must be sent to the plaintiff's attorney or plaintiff (if unrepresented) Peter A. Sandberg, whose address is: 813 W. Third Avenue
Anchorage, Alaska 99501

If you fail to file your answer within the required time, a default judgment may be entered against you for the relief demanded in the complaint.

If you are not represented by an attorney, you must inform the court and all other parties in this case, in writing, of your current mailing address and any future changes to your mailing address and telephone number. You may use court form *Notice of Change of Address / Telephone Number* (TF-955), available at the clerk's office or on the court system's website at www.courts.alaska.gov/forms.htm, to inform the court. - OR - If you have an attorney, the attorney must comply with Alaska R. Civ. P. 5(j).

NOTICE OF JUDICIAL ASSIGNMENT

TO: Plaintiff and Defendant

You are hereby given notice that:

- ☒ This case has been assigned to Superior Court Judge Miller
and Master _____
☐ This case has been assigned to District Court Judge _____

CLERK OF COURT

5/8/19
Date



By: Vadine
Deputy Clerk

I certify that on 5/8/19 a copy of this Summons was ☐ mailed ☒ given to
☐ plaintiff ☒ plaintiff's counsel along with a copy of the
☐ Domestic Relations Procedural Order ☐ Civil Pre-Trial Order
to serve on the defendant with the summons.
Deputy Clerk VV

* The State or a state officer or agency named as a defendant has 40 days to file its answer. If you have been served with this summons outside the United States, you also have 40 days to file your answer.

CIV-100 ANCH (6/10)(st.3)
SUMMONS

Civil Rules 4, 5, 12, 42(c), 55

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Attorneys for Plaintiff

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT AT ANCHORAGE

MARY F. SILVA

Plaintiffs,

v.

HOWMEDICA OSTEONICS CORP
d/b/a STRYKER
ORTHOPAEDICS

Defendant.

COPY
Original Received

MAY - 8 2019

Clerk of the Trial Courts

Case No. 3AN-19-6884 Civ.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all issues so triable in her civil action.

Dated this 7th day of May, 2019.

INGALDSON FITZGERALD, P.C.
Attorneys for Plaintiffs

By: 

Peter A. Sandberg
ABA No. 0611084

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Case No. 3AN-19-____ CIV
Demand for Jury Trial

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COMPLAINT

Comes now plaintiff, Mary Silva, by and through her counsel of record, Ingaldson Fitzgerald, P.C., and asserts as follows:

PARTIES

1. Plaintiff, Mary Silva, is, and at all relevant times to this claim was a resident of Seward, Alaska.

3. Defendant Howmedica Corporation (hereinafter "Howmedica") is a Michigan corporation with its principle place of business located at 2825 Airview

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Boulevard, Kalamazoo Michigan 49002, and conducts business throughout the United States, including the State of Alaska by developing, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, selling, and/or otherwise placing into the stream of commerce the Defective Device in a manner reasonably calculated to reach and impact the general public in the State of Alaska, including Plaintiffs.

4. Defendant Stryker Osteonics Corp d/b/a/ Howmedica Orthopaedics (hereinafter "Howmedica") is a New Jersey Corporation with its principle place of business located at 325 Corporate Drive, Mahwah, New Jersey 07430, and conducts business throughout the United States, including the State of Alaska by developing, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, selling, and/or otherwise placing into the stream of commerce the Defective Device in a manner reasonably calculated to reach and impact the general public in the State of Alaska, including Plaintiffs.

5. Defendant Stryker and Defendant Howmedica are hereinafter collectively referred to as the "Howmedica Defendants".

JURISDICTION AND VENUE

6. Venue is proper in this Court in that at present and at all material times relevant to this action Howmedica had and has substantial, continuous, and systematic contacts in the State of Alaska and/or committed a tort in whole or in part in the State of Alaska. Pursuant to AS 22.10.030 and Alaska Rules of Civil Procedure 3 venue is proper.

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7. This court has subject matter jurisdiction because the Defendant does business in the State of Alaska, and the harm caused by the Defendant to Plaintiff occurred in the State of Alaska.

FACTUAL ALLEGATIONS

8. This product liability action relates to the design, development, manufacture, testing, marketing, promotion, distribution and sale of Howmedica's defective hip components, which includes a "Chrome Cobalt femoral head and a Chrome Cobalt femoral stem". At all times relevant to this Complaint, Howmedica regularly engaged in business in the State of Alaska.

9. At all times relevant to this Complaint, Howmedica placed the "Chrome Cobalt femoral head and stem" as part of their "Hip Joint Replacement System components" (hereinafter "Defective Products") into the stream of interstate commerce.

10. At all relevant times, Howmedica expected or should have expected that its acts and omissions would have consequences within the State of Alaska.

11. Plaintiff's damages in this matter accrued in the State of Alaska.

12. Total hip arthroplasty, commonly referred to as hip replacement surgery, is the term used to describe the surgery wherein a patient's natural hip anatomy is replaced with synthetic components. A patient may need a total hip arthroplasty for a variety of medical reasons including degenerative bone disease and avascular necrosis.

13. The hip joint connects the thigh (femur) bone of a patient's leg to the patient's pelvis. The hip joint is often characterized as a ball and socket joint. The

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acetabulum is the cup shaped socket portion of the hip and the femoral head (ball) at the top of the femur bone rotates within the curved surface of the acetabulum.

14. A total hip replacement replaces the body's natural joint with an artificial one, usually made out of metal, plastic, or ceramic. A total hip replacement typically consists of four separate components: (1) a femoral stem, (2) a femoral head, (3) an acetabular liner, and (4) an acetabular shell. After the surgeon hollows out a patient's femur bone, the metal femoral stem is implanted. The femoral head is usually a metal or ceramic ball that is fixed on top of the femoral stem. The femoral head forms the hip joint that can rotate when it is placed inside a plastic or ceramic acetabular liner that is attached to the interior portion of the metal acetabular shell comprised of metal on its outer surface. When complete, the femoral stem anchors the femoral head that rotates within the acetabular liner sitting inside the acetabular shell. Historically, femoral heads and stems were not made with chrome and cobalt.

15. At all times material hereto, the Howmedica Defendants developed, designed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, promoted, marketed, supplied, sold and/or warranted the Defective Devices either directly or indirectly, to members of the general public throughout the United States in and the State of Alaska, including to Plaintiff.

16. The Defective Devices are modular femoral hip replacement devices to be used in total hip replacement surgery. They are indicated for patients requiring primary total hip arthroplasty due to painful joint disease of the hip resulting from non-inflammatory degenerative arthritis including osteoarthritis and avascular necrosis.

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17. As noted, the Defective Devices are critically different from most traditional hip replacement products, as they are modular in nature, and made of a Chromium/ Cobalt combination. A chrome cobalt femoral head which is placed on a selected chrome cobalt femoral stem and then inserted into a Trident Cluster Acetabular shell, which has a liner.

18. The defective design and manufacture of the Defective Devices allows fretting and corrosion to occur at the taper junctions between the femoral head and the femoral stem of the hip replacement components. The fretting and corrosion allows metal ions, including cobalt and chromium, to be released into the surrounding tissues. The fretting and corrosion and release of ions also manifest in increased cobalt and chromium blood levels of the patient. These cobalt and chromium ions destroy surrounding tissue and bone often causing pseudotumors and a condition called metallosis.

19. Prior to January of 2009, defendant Howmedica manufactured the following components:

a. A Stryker Trident PSL Cluster Acetabular Shell size 54mm Alpha code F (Lot number 3JKNME; Reference No. 542-11-54F);

b. An HDFX Plus 127 Neck Angle V40 Hip stem size #3 (Lot Number 4LOMED; Reference Number 6077-00335);

c. An LFIT Anatomical V40 femoral Head 36 MM (Lot number KV7MNE; Reference No; 6260-9-136);

d. A Trident X3 Polyethelene Insert 36 MM (Lot number R66MAE; Reference No 623-00-36F;

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These components, hereinafter referred to as "Defective Products" were surgically implanted in Mary Silva's left hip by Dr. Stephen Tower at Providence Alaska Medical Center in Anchorage, Alaska on January 9th, 2009.

21. Following her surgery, Mary Silva followed her physician's orders, and returned for follow up care as ordered.

22. On or about May 15, 2018, Mary Silva followed up with Dr. Stephen Tower of Tower Joint Replacement Clinic. She was experiencing significant pain in her left hip, and was experiencing other symptoms of metallosis poisoning.

23. Lab testing of Mary Silva's blood and urine showed the presence of elevated Cobalt and Chromium. Additionally, radiology studies showed the presence of pseudo tumors at the right hip implant site. She underwent PET scan testing which demonstrated significant cerebral changes.

24. On or about June 21, 2018 Mary Silva underwent a revision surgery for her left hip, in which the Howmedica chrome cobalt head was replaced with a Delta ceramic head. She underwent this surgery at Alaska Regional Hospital in Anchorage, Alaska. Her surgeon, Dr. Stephen Tower, found signs of metallosis, which included black corrosion debris, damaged hip ligaments, the presence of pseudo tumors and metal debris at the hip/ neck junction.

25. The metallosis, corrosion debris, damaged hip ligaments, pseudo tumors neuropathy, cognitive dysfunction and other damages, which necessitated a revision surgery, were caused by the defective Howmedica hip components.

CAUSES OF ACTION

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COUNT I
(Strict Liability, Defective Design and Failure to Warn)

26. Plaintiff incorporates by reference, paragraphs 1 through 25 above, as if fully set forth herein.

27. At all times material hereto, Howmedica engaged in the business of developing, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, retailing, supplying and/or selling the Defective Product and through that conduct placed the Defective Product into the stream of commerce in the State of Alaska.

28. On information and belief, the Defective Product was defective at the time of its manufacturer and marketing.

29. The Defective Product was defectively designed and/or manufactured so as to be unreasonably dangerous to consumers.

30. The Defective Product was intended for use in hip replacement procedures for consumers. Ms. Silva became a consumer and relied upon the safety of the manufacturing Defendant's product.

31. Howmedica failed to warn the public, including Plaintiff, of the risk of suffering the type and manner of injuries suffered by Plaintiff, which risks and/or dangers were known or should have been known to Howmedica.

32. Howmedica developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, retailed, supplied and/or sold the Defective Product, including the promotional materials, publicity and/or information to Plaintiffs,

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including but not limited to, the information printed on the instructions for use, labeling and/or packaging.

33. Defendants expected their Defective Product to reach, and it did in fact reach, consumers in the State of Alaska, including Plaintiff, without substantial change in its condition.

34. At all relevant times, the Defective Product (including the sales and promotional materials) developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, retailed, supplied, and/or sold by Howmedica were defective including one or more of the following particulars:

a. Howmedica's Defective Product contained unreasonably dangerous design defects and were not reasonably safe as intended to be used, subjecting Plaintiff to risks which exceeded the benefits of the device;

b. Howmedica's Defective Product was defective in design and formulation, making use of the product more dangerous than the ordinary consumer would expect;

c. Howmedica's Defective Product contained insufficient and/or incorrect warnings to alert consumers and users, including Plaintiff, of adverse effects and risks thereto;

d. Howmedica's Defective Product was not safe for its intended use;

e. Howmedica's Defective Product was inadequately tested;

f. Howmedica's Defective Product was not accompanied by adequate instructions and/or warnings to fully apprise the implanting and/or prescribing physicians

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as well as the ultimate consumers, including Plaintiff, of the full nature or extent of the risks and side effects associated with its use.

35. Howmedica knew and intended that its Defective Product would be purchased from Howmedica by members of the general public and would be used by such purchasers without any inspection for defects, and would rely upon the representations made by Howmedica on the product label, and in other promotional and sales materials.

36. At the time of manufacture and sale to Plaintiff, the Defective Product was unsafe and defective to consumers using the product for its advertised purposes and in a reasonably foreseeable manner, in that it posed an unreasonably high risk of serious injury to consumers, which information was concealed by Howmedica.

37. Prior to the manufacturing, sale and distribution of the Defective Product, Howmedica knew, or was reckless in not knowing, that the product was in a defective condition and that those who were implanted with such device were at an unreasonable risk of experiencing injury.

38. Plaintiff used the device for its intended purpose.

39. Plaintiff could not have discovered any defect in the Defective Product or accompanying sales and promotional materials through the exercise of due care.

40. Howmedica as a manufacturer, marketer, retailer, distributor and seller of the Defective Product and like products is held to the level of knowledge of an expert in the field.

41. Plaintiff did not have substantially the same knowledge, as an adequate warning from Howmedica should have communicated.

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42. As a direct and proximate result of Howmedica placing the Defective Products into the stream of commerce, Plaintiff Mary Silva has suffered and continues to suffer both injuries and damages in the State of Alaska, including but not limited to: past, present, and future physical and mental pain and suffering; and past, present and future medical, hospital, monitoring, and rehabilitative expenses.

COUNT II

(Breach of Express and Implied Warranties)

43. Plaintiff incorporates by reference, paragraphs 1 through 42 above, as if fully set forth herein.

44. At the time and place of the sale, distribution and supply of the Defective Product to Plaintiffs, Howmedica expressly represented and warranted that its product was safe, and impliedly warranted that the product was reasonably fit for its intended purpose and was of marketable quality.

45. Howmedica's Defective Product was unfit and unsafe for use by users as it posed an unreasonable and extreme risk of injury to persons using said product, and accordingly Howmedica breached both express and implied warranties.

COUNT III

(NEGLIGENCE)

46. Plaintiff incorporates by reference, paragraphs 1 through 45 above, as if fully set forth herein.

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47. Howmedica was under a duty to use reasonable care in the design, manufacture, and the provision of warnings accompanying the Defective Products.

48. Howmedica was under a duty of care in the distribution and sale of its Defective Products so that they would be reasonably safe for their intended use.

49. Howmedica breached this duty by, among other things:

a. Failing to exercise care in designing, developing, manufacturing, retailing, distributing and selling its Defective Products so as to avoid the above risks to individuals using the product;

b. Failing to include adequate warnings with its Defective Products which would alert Plaintiffs and other consumers to its potential risks and serious side effects;

c. Failing to adequately and properly test its Defective Products before placing them into the stream of commerce;

d. Failing to conduct sufficient testing on its Defective Products, which if properly performed, would have shown that the products had serious side effects, including, but not limited to, loosening and causing pain and discomfort in the hip;

e. Failing to provide adequate post-marketing warnings or instructions after Howmedica knew, or should have known, of the significant risks of injuries and events from the use of the Defective Products.

50. As a direct and proximate result of Howmedica's negligence, plaintiffs sustained injuries and damages which will be proven with more specificity at trial.

COUNT IV

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(MISREPRESENTATION)

51. Plaintiff incorporates by reference, paragraphs 1 through 50 above, as if fully set forth herein.

52. At all relevant times, Howmedica represented to Plaintiff directly and/or through their agents, servants and representatives, that the Defective Products were fit for intended uses and would otherwise benefit users.

53. Howmedica made such representations, knowing they were false and that Plaintiffs would rely upon same.

54. Ms. Silva did, in fact, rely upon Howmedica's representation to his detriment.

55. Ms. Silva's reliance upon such statements was reasonable.

56. As a direct and proximate result of Howmedica's misrepresentations, plaintiff suffered injuries and damages which will be proven with more specificity at trial.

COUNT V
**(THE ALASKA UNFAIR TRADE PRACTICES
AND CONSUMER PROTECTION ACT)**

57. Plaintiff incorporates by reference, paragraphs 1 through 56 above, as if fully set forth herein.

58. At the time Howmedica manufactured, designed, marketed, sold and distributed the Defective Device for use by Plaintiff, Howmedica knew or should have known of the use for which the Defective Devices were intended and the serious risks and dangers associated with such use of the Defective Devices.

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59. Howmedica owed a duty to treating physicians and to the ultimate end-users of the Defective Devices, including Plaintiff, to accurately and truthfully represent the characteristics, ingredients, uses, benefits, quality, standards and/or risks of the Defective Devices.

60. Howmedica breached that duty by misrepresenting the characteristics, ingredients, uses, benefits, quality, standards and/or risks of the Defective Devices.

61. Howmedica's misrepresentations were unfair methods of competition and/or unfair or deceptive acts or practices, and a breach of the Alaska Unfair Trade Practices and Consumer Protection Act ("UTPA") as set forth, without limit, in AS § 45.50.471(b)(4), (6), (11) and (12).

62. As a direct and proximate result of Howmedica's wrongful conduct, Plaintiff sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses, and other damages for which she is entitled to compensatory damages in an amount to be proven at trial.

63. As a direct and proximate result of Howmedica's breach of obligations under the UTPA, Plaintiff is entitled to recover treble damages. *See* AS § 45.50.531(a).

64. As a direct and proximate result of Howmedica's breach of obligations under the UTPA, Plaintiff is entitled to recover actual attorney's fees. *See* AS § 45.50.537(a).

65. The cause of action set forth in this Count is not preempted by 21 U.S.C. § 360k because the violations alleged are all based on an exclusively federal statutory and regulatory set of requirements which include no "requirement which is different from, or

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in addition to, any requirement applicable under” the Act and regulations promulgated thereunder. See *Bausch v. Howmedica*, 630 F.3d 546, 556 (7th Cir. 2010) (claims for negligence and strict products liability relating to a Class III medical device were not expressly preempted by federal law to the extent they were based on the defendants’ violations of federal law). As such, the claims set forth in this cause of action contain requirements that are parallel to the Act and regulations promulgated thereunder.

COUNT VI
(PUNITIVE DAMAGES)

66. Plaintiff incorporates by reference, paragraphs 1 through 65 above, as if fully set forth herein.

67. Prior to the manufacturing, sale and distribution of the Defective Products, Howmedica knew, or was reckless in not knowing, that the products were in a defective condition and that those who were implanted with such devices were at an unreasonable risk of experiencing injury. Howmedica through its officers, directors and managing agents, had notice and knowledge from several sources, prior to the date of marketing and sale of the Defective Products to Ms. Silva, that the products presented a substantial and unreasonable risk of harm to the consumer, including Ms. Silva, and as such said consumers were unreasonably subjected to risk of injury from the use of those products.

68. Despite such knowledge, Howmedica, through its officers, directors and managing agents, knowingly and deliberately failed to remedy the known defects in its

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product and failed to warn the public, including Ms. Silva, of the serious risk of injury occasioned by the defects inherent in the Defective Products.

69. Upon information and belief, Howmedica's failure to notify the public, including Ms. Silva was for the purpose of increasing sales and enhancing their profits and Howmedica intentionally proceeded with manufacturing, selling and marketing of the Defective Products knowing that persons would be exposed to serious potential danger, in order to advance their own pecuniary interests.

70. The actions of Howmedica as noted herein were outrageous and demonstrated reckless indifference to the welfare of the intended users of the Defective Products, and was done so as to profit its own self-interests and as such warrant exemplary damages.

WHEREFORE, Plaintiff prays for the following relief:

1. For a judgment against Defendant Howmedica and in favor of plaintiffs, and in an amount in excess of \$100,000, the exact amount to be proven at trial;
2. For prejudgment interest, punitive damages, costs and attorney's fees; and
3. For such other and further relief as this court deems just and equitable.

RESPECTFULLY SUBMITTED this 7th day of May, 2019.

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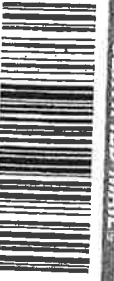
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